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Title: MEDICAL DEVICE :

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Inventor(s): LOPEZ GEORGE A (US) ;

Applicant(s): ICU MEDICAL INC (US) ;

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ABSTRACT:

Disclosed is a medical device used with a syringe or the like that includes a needle protected by a guard. The needle has a connector at one end opposite its tip which enables it to be connected to the syringe. The guard is mounted on the needle and is movable axially along the shaft of the needle between a retracted position enabling the needle to be inserted into a patient and a forward position covering the tip of the needle. The guard is moved forward manually from the retracted to the forward position by the nurse after using the needle to protect the nurse against accidental needle sticks. The forward manner in which the guard is moved by the nurse eliminates the possibility of the nurse being accidentally stuck by the needle when covering the tip with the guard, because the forward movement is along the needle shaft and not inwardly toward the needle tip as with conventional practice.

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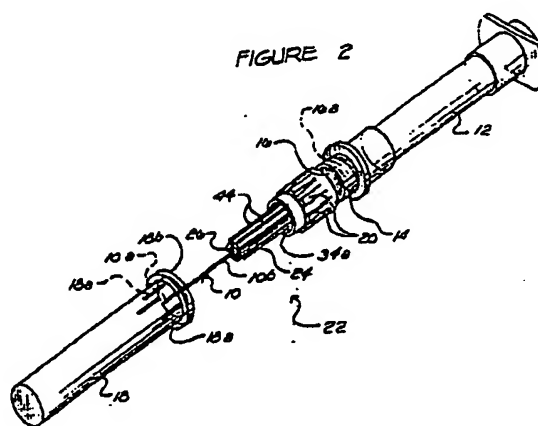
(71) Applicant: ICU Medical, Inc.
23436 Madero Street
Mission Viejo, CA 92692(US)

(72) Inventor: Lopez, George A.
3731 Seascap Drive
Huntington Beach, CA 92649(US)

(74) Representative: Altenburg, Udo, Dipl.-Phys. et al
Patent- und Rechtsanwälte
Bardehle-Pagenberg-Dost-Altenburg-Frohwi-
tter & Partner Postfach 86 06 20
D-8000 München 86(DE)

(54) Medical device.

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EP 0 240 987 A2

MEDICAL DEVICE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to medical devices used with, for example, syringes and intravenous (IV) medication dispenser sets and, in particular, relates to a device for enclosing a needle after it has been used so that the needle will not accidentally stick the user.

2. Background Discussion

Many medications are administered by injecting the medication through a needle that has penetrated the body of the patient. The needle is usually removeably attached to a medication dispenser such as an IV set or syringe. When the needle is attached to a syringe, the nurse manually activates a plunger which forces the medication from the syringe through the needle, out the tip of the needle, into the body of the patient. It is common practice to use disposable needles. After the needle has been used, the nurse detaches the needle from the syringe and discards it. In many instances the nurse will clip the needle, rendering it unsuitable for subsequent use.

The needles commonly employed are contained within a sheath made, for example, of plastic. This sheath grips the needle in a fashion that allows the nurse, while holding the sheath, to attach the needle to the delivery end of the syringe. Ordinarily a Luer lock, or other type of conventional threaded device, is employed which allows the nurse to simply screw the needle onto the delivery end of the syringe. With the needle attached to the syringe, the nurse removes the sheath, exposing the needle. After the needle has been used to inject medication into the patient, the nurse frequently will replace the sheath covering the needle. Ribs on the inside of the sheath engages splines on the barrel hub of the needle upon rotation. The nurse then rotates the sheath and to detach the needle from the syringe. All too frequently in the act of resheathing the needle, the nurse accidentally sticks herself. If the patient is carrying a highly infectious disease, the nurse could be infected. Consequently, a blood test must be conducted on the nurse to see if she is already carrying the disease. This is necessary because if she is not infected at the time of the stick, her employer, the hospital, will be liable.

Accidental needle sticks have been recognized as a serious health hazard and are discussed in U. S. patent application Serial No. 06/606,679, filed May 3, 1984, entitled Medical Connector, assigned to the same assignee as this patent application. This medical connector employs a needle housed within a cap member so that the nurse is protected against accidental needle sticks. This connector, however, is not suitable for directly administering medication to the patient through a needle which is inserted into the body of the patient. Others have suggested that a protective sheath for the needle be attached to the syringe and movable to cover the needle when the needle is not in use and then retracted to expose the needle. Such devices are illustrated in U. S. Patent Nos. 4,425,120 and 2,571,653, and 3,134,380, and 2,925,083. These devices, however, all contemplate repeated use of the needle. This would require resterilization after each use and is not consistent with current medical practices which employ disposable needles.

MAJOR FEATURES OF THE INVENTION

The problems discussed above have been obviated by the present invention which provides a simple, safe, and convenient way to protect the user against needle sticks after the needle has been used to inject medication into a patient. There are several features of this invention, no single one of which is solely responsible for its desirable attributes. Without limiting the scope of this invention, as expressed by the claims, its more prominent features will now be discussed briefly. After considering this discussion, and particularly after reading the section of this application entitled "Detailed Description of the Preferred Embodiment," one will understand how the features of this invention provide the advantages of simplicity, convenience, and safety.

One feature of the present invention is that the needle is covered with a guard after being used. The needle is secured to a connector which is adapted to be removably detached to the medication dispenser. This allows the needle to be detached and disposed after it is used. The guard is manually movable and mounted along the needle. It moves axially between a first position where the tip of the needle is exposed to a second position where the guard covers the tip of the needle and prevents needle sticks.

In accordance with another feature of this invention, locking means are mounted along the needle which permanently locks the guard in the second position upon movement of the guard from the first position to the second position. Because the guard is locked in position, there is no chance that the nurse can be stuck with the needle after she uses it. The guard is a tubular element and it has a collar at its rearward end. Associated with the guard are means which releasably hold the guard in the first position so that the nurse may apply a minimum force to overcome the grip of the holding means. After using the needle, the nurse pushes the guard towards the tip of the needle to move it to the second position. The locking means includes a receptacle for the collar and a stop which limits the forward movement of the guard. When the guard has been moved forward, the collar engages the stop and snaps into locking position in the receptacle. In this position the tip of the needle is covered by the guard. The guard has an opening in its forward and rear end which allows the guard to move axially along the needle shaft. Thus the needle tip is exposed when the guard is in the first position, but permits the guard to be pulled over the tip upon forward movement of the guard. The opening at the forward end of the guard is restricted so that a nurse will not be able to stick his or her little finger through the opening and be pricked by the tip of the needle when the guard is in the second position.

The medical device of this invention is made out of conventional plastic materials which are molded into the desired shapes, with the needle being conventional, made of a metal such as stainless steel. The device is easy to manufacture, is inexpensive, and most importantly, provides a safe way of protecting nurses against sticks from needles which have been used in administering medication to patients carrying highly infectious diseases. Once the needle has been used, the nurse simply moves the protective guard into position covering the needle, detaches the needle from the medication dispenser, and disposes of it by placing it in the suitable waste container. She does not need to clip the needle, because the guard is now permanently locked into position and one could only remove the guard by destroying the structure of the device.

The preferred embodiment of this invention illustrating all its features will now be discussed in detail. This embodiment shows the device of this invention being used with a conventional syringe. It could be used in any application where it is desired to protect a needle after it has been inserted into a patient and it is no longer desired to reuse such needle.

BRIEF DESCRIPTION OF THE DRAWINGS

The medical device of this invention is illustrated in the drawing, with like numerals indicating like parts, and in which:

FIG. 1 is an exploded perspective view of the conventional way of covering the disposable needle used with a syringe.

FIG. 2 is an exploded perspective view of the medical device of this invention.

FIG. 3 is a side elevational view, with sections broken away, of the medical device of this invention, with the sheath for the device in position and the guard for the needle in a retracted position.

FIG. 4 is a side elevational view of the device shown in FIG. 3, with the sheath removed.

FIG. 5 is a side-elevational view of the device shown in FIG. 4, with the guard moved to a forward position to cover the tip of the needle.

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 5.

FIG. 7 is an enlarged fragmentary view, in cross-section, of the rear end of the device of this invention, with the guard in the retracted position.

FIG. 8 is an enlarged fragmentary view in cross-section of an intermittent portion of the device, with the guard in the retracted position.

FIG. 9 is a cross-sectional view taken along line 9-9 of FIG. 8.

FIG. 10 is an enlarged fragmentary view of the rear end of the guard.

FIG. 11 is a cross-sectional view taken along line 11-11 of FIG. 10.

DESCRIPTION OF THE PREFERRED EMBODIMENT

As illustrated in FIG. 1, the conventional practice for injecting medication into the body of the patient calls for a metal needle 10 to be removably attached to a syringe 12. This needle 10 has a plastic hub 14 with dog ears (not shown) that are threaded into a threaded delivery end 16 of the syringe. The needle 10 is ordinarily initially enclosed in a plastic sheath 18 which fits snugly about the hub 14. Needles 10 come in many different sizes, both in diameter and length, and they are enclosed individually within sheaths. The nurse selects which size needle to use in administering the medication and grasps the sheath 18 with one hand and then simply screws the needle 10 into position by inserting the hub 14 into the delivery end 16 of the syringe 12 and turning the sheath. The sheath 18 carries on its internal wall splines 18a which engage ribs 20 on the hub 14, enabling the sheath and needle to be rotated as a unit. With rotation, the dog ears slide into threads 16a in end

16 to lock the needle 10 on to the syringe 12. The nurse then pulls the sheath 18 off the hub 14, exposing the needle. She then inserts the needle 10 into the body of the patient, depresses a plunger (not shown) of the syringe 12 to force liquid medication through the needle, out of the needle tip 10a and into the patient and then pulls the needle from the patient. Normally the nurse will replace the sheath 18, inserting the needle 10 into the open mouth 18b of the sheath. It is at this point that accidents commonly occur. If the nurse is distracted, has poor eyesight, or is simply inattentive, she may stick herself with the needle 10. If the needle 10 has just been used to inject medication into a patient infected with a highly contagious disease, it is likely that the nurse will contract the disease if she accidentally sticks herself with the needle. If she does manage to replace the sheath 18 on the needle 10 without sticking herself, she then detaches the needle 10 by turning the sheath with the hub 14 of the needle inserted snugly into open mouth 18b of the sheath 18. Rotation then occurs between the needle hub 14 and the delivery end 16 of the syringe 12 to detach the needle 10 from the syringe. In many instances, the nurse is required by hospital protocols to clip the needle before she disposes of it. This is to prevent reuse of the needle 10. Such clipping of the needle 10 creates an aerosol which may contain infectious microbes that could be inhaled by the nurse or others in the vicinity. This unsafe practice of clipping the needle and recovering it is not eliminated by the present invention.

As illustrated in FIG. 2, the medical device 22 of this invention includes a hub 14 having dog ears 14a (FIG. 7) at one end which allow the device 22 to be removably attached to the end of the syringe 12. Extending from this hub 14 is the elongated metal needle 10 of any desired length and thickness. Attached to the shaft 10a of the needle 10 is a movable guard 24 which moves axially along the shaft of the needle from a rearward position, as illustrated in FIG. 4, to a forward position, as illustrated in FIG. 5. In the forward position, the guard 24 is locked in place by means of a locking element 26 mounted to the shaft 10a of the needle 10. As best illustrated in FIG. 3, prior to use, the guard 24 is in the retracted position and the sheath 18 encases both the needle 10 and the guard.

As best shown in FIG. 7, the barrel hub 14 is molded from any suitable plastic and it has a sheath carrier forward section 14a. This section 14a preferably has a tapered side wall 14b which allows the barrel hub 15 to be inserted into the open mouth 18b of the sheath 18, with the inside wall of the sheath sitting snug against the side wall of section 14a to hold the cover in position. The barrel hub 14 has a generally cylindrical configuration and

has a passageway 28 extending from the end of the hub connected to the syringe 12 to the end of the hub carrying the needle. This passageway 28 is centrally located along the longitudinal axis of the hub 14 and provides a conduit for the medication to flow from the syringe 12 into the needle 10.

The hub 14 includes a fluid reservoir 30, with the passageway 28 having a series of parallel bores 28a running about the passageway. The passageway 28 ends in a funnel-like open section 32. One end of the needle 10 is inserted into the passageway 28 and stops at the base of the reservoir 30. An adhesive 33 is inserted through the open section 32 and flows around the outside wall of the needle shaft 10a and into the bores 28a filling them. On curing, the adhesive 33 bonds the needle 10 into position securely.

The end of the barrel hub 14 opposite the reservoir 30 includes a cavity 34 with an open mouth 34a into which the rear of the guard 24 will pass. The cavity 34 is formed by an annular recess within the hub section 14a. There is formed by an annular recess within the hub section 14a. There is a circumferential groove 36 adjacent the mouth 34 which engages a row of spaced nipples 38 (FIG. 10) carried on the exterior of the rear end of the guard 24. Centrally located, and integral with the hub section 14a, is a neck portion 14c through which the passageway 28 extends. This neck portion 14c is of a generally cylindrical configuration.

The guard 24 is a generally hollow cylindrical member made of plastic having at its rear end a collar member 40 in the form of an annular wall which is received within the cavity 34 when the guard is in the retracted position. The neck member 14c extends through an opening 40a in the collar 40, with the internal annular surface of the collar abutting the external surface of the neck 14c. The guard 24 has an open end 24a (FIG. 8) which is sufficiently restricted so that a typical adult user cannot insert his or her finger through this opening and contact the tip 10a of the needle 10. Typically the diameter of this opening is less than one centimeter and the tip 10a of the needle is displaced inwardly from this opening a minimal distance of one-half centimeter.

As best illustrated in FIGS. 10 and 11, the rear end of the guard 24 has four equally spaced slits 42 extending lengthwise from the rear end to about the nipples 38. Each slit 42 terminates in a beveled end. These slits divide the collar 40 into four equal segments, which will flex outwardly, enlarging the opening 40a as the guard 24 engages the locking element 26. This feature will be explained in greater detail subsequently. A series of parallel ribs 44 molded in the exterior surface of the guard 24 to provide means for facilitating grasping and holding the guard. At the open end 24a of the guard 24 is

an annular ridge 46 carried on the inside wall of the guard. This ridge has tapered side walls which are received in a corresponding tapered groove 48 in the locking element 26. The nipples 38 and ridge 46 hold the guard 24 in the rearward position until the nurse manually moves the guard forward to the position shown in FIG. 5. Thus there is enough play to allow the guard to be moved forward manually, but sufficient tightness so that the guard will not accidentally jar loose, for example, during shipment.

The locking for the guard 24 is best illustrated by FIGS. 8 through 11. The locking element as shown in FIGS. 8 and 9 includes a body member 50 having a conical-like end portion 52 which provides a ramp over which the collar 40 rides as the guard is moved to the fully extended forward position. This ramp terminates in an annular rear shoulder 54. At the other end of the body member 50 is an annular front shoulder 56. The front shoulder 56 is higher than the rear shoulder 54 and its diameter is just slightly less than the diameter of the open mouth 24a of the guard. Between the shoulders 54 and 56 is a receptacle portion 58 which consists of an annular recess running about the central portion of the body member 50 having a base 58a and opposed inwardly tapered rear and front walls 58b and 58c. The collar 40 drops into this receptacle portion 58 when the guard 24 is moved to the fully extended forward position shown in FIG. 5. The collar segments spread apart slightly as the guard 24 moves up the ramp end 52. Thus, the opening 40a in the collar 40 expands slightly to allow this end 52 to pass through this opening with the collar riding up and over the shoulder 54. When the collar 40 is opposite the receptacle portion 58, the opening 40a will resume its ordinary diameter and the collar 40 drops into the receptacle portion, with the front tapered wall 58c acting as a stop which abuts the collar. Once the collar 40 is in the receptacle portion 58, the guard is permanently locked into position so that it cannot move rearwardly to return to the position shown in FIG. 4.

OPERATION

To use of the medical device of this invention, one would first attach it to the delivery end 16 of the syringe 12, as shown in FIG. 3, inserting the dog ears 14a into the threads 16a in delivery end of the syringe and turning the device 22 to screw it in position. The nurse would then remove sheath 18 by simply pulling it off the barrel hub 14.

The tip 10a of the needle 10 is now exposed, as shown in FIG. 4. The nurse then penetrates the body of the patient, depresses the plunger of the syringe 18 to force medication through the pas-

sageway 28 and out of the tip 10a of the needle into the body of the patient. After the medication has been administered to the patient, the nurse pulls the needle from the patient. Instead of placing the sheath back on the device 22, the nurse simply grasps an intermediate portion of the guard 24, which is in the position illustrated in FIG. 4, and pushes it forward in a smooth, one stroke motion. Even if the nurse's hand slipped from the guard 24, her fingers would simply ride down the shaft 10b of the needle 10 and over the tip 10a of the needle, without sticking herself. This is contrary to the conventional practice where the nurse's hand moves in a direction towards the tip 10a of the needle 10.

As the nurse pushes the guard, it will move to the right, as shown in FIG. 4, moving from the retracted position, as shown in FIG. 6, to the forward position, as shown in FIG. 5. When the nurse initiates this movement of the guard 24, the nipples 38 slips from the groove 36 and the ridge 46 slips from the groove 48. The shoulder 56 of the locking member provides stability and guidance for the guard 24 as it moves along the shaft 10b of the needle 10. When the collar engages the ramp end 52, the tip of the ramp end is inserted into the opening 40a, spreading the collar apart, slightly enlarging this opening 40a as the collar rides up the ramp and over the rear shoulder 54. When the collar 40 is opposite the receptacle portion 58, the opening will once again close and the collar 40 will snap into the receptacle portion. Because of the tapered sidewalls of the walls of the receptacle portion and corresponding tapered walls of the collar the guard is locked into position. Thus, even if the nurse attempted to retract the guard by moving it to the position shown in FIG. 4, the collar 40, locked into position in the receptacle portion 58, will prevent the guard 24 from being returned to the retracted position. Thus, the guard 24 is permanently locked into position, protecting the nurse against accidental needle sticks. Because the guard 24 cannot be moved without destroying the entire structure of the device 22, and destroying the needle, it is not necessary to clip the needle. Thus a dangerous germ containing aerosol is not sprayed into the atmosphere.

SCOPE OF THE INVENTION

The above description presents the best mode contemplated upon carrying out the present invention. This invention is, however, susceptible to modification and alternate constructions from the embodiments shown in the drawing and described above. Consequently, it is not the intention to limit this invention to the particular embodiments dis-

closed. On the contrary, the intention is to cover all modifications and alternate constructions coming within the spirit and scope of the invention as expressed by the claims.

Claims

1. For use with a medication dispenser, the combination including
connector means which is adapted to be removably attached to the syringe;
an elongated needle having a tip and a rear end secured to the connector means, said needle being in communication with the dispenser upon attachment of the connector means to the syringe so that the medication contained within the syringe will flow from the syringe through the needle and out said tip;
manually movable guard means mounted along the needle to move between a first position with the guard means rearwardly from the tip so that the tip of the needle is exposed and a second position where the guard means covers said tip to prevent needle sticks, and
locking means mounted along said needle which permanently locks the guard means in the second position upon movement of the guard means from the first position to the second position.

2. The combination of Claim 1 wherein the guard means is a tubular element having a collar member at the rearward end and a restricted opening at the forward end, said needle extending through the opening in the forward end when the guard means is in the first position to expose the needle tip.

3. The combination of Claim 2 including means which releasably holds the guard means in the first position until the user manually moves said guard means from the first position to the second position.

4. The combination of Claim 2 wherein the opening in the guard means has a maximum width that does not exceed about one centimeter.

5. The combination of Claim 2 wherein the needle is recessed within the guard means when said guard means is in the second position so the tip of the needle is displaced inwardly from the opening a minimum distance of about one-half centimeter.

6. The combination of Claim 2 wherein the collar has an orifice therein and the connector means includes a neck portion fitting through said orifice when the guard means is in the first position.

7. The combination of Claim 1 wherein the connector means includes a hub portion having one end thread means for engaging thread means

on the dispenser to enable the connector means to be attached to the dispenser by screwing the connector means on to the syringe.

8. The combination of Claim 6 including a sheath member which fits over the needle when the guard means is in the first position to prevent exposure of said tip, said sheath member having one end closed and opposed to said open end a closed end, said hub portion fitting snugly into the open end so that the sheath member encases the needle and guard means but may be manually removed by pulling it off the hub portion.

9. The combination of Claim 7 wherein the hub portion has an annular recess in an end opposed to the end carrying thread engaging means to provide a cavity having an open mouth and a neck portion lodged centrally within the cavity and displaced inwardly from said open mouth of the cavity.

10. The combination of Claim 9 wherein the guard means is an elongated hollow cylindrical element having an annular collar member at its rearward end which fits into the annular cavity when the guard means is in the first position.

11. A medical device including
a metal needle having one end adapted to be placed in communication with a source of medication, a hollow shaft through which the medication flows, and an open tip adapted to penetrate the body of the patient and from which the medication exits the needle;
a guard member mounted on the shaft of the needle and movable axially along the shaft between a first position where the guard means is displaced inwardly from the tip to expose said tip to enable it to penetrate the body of a patient and a second position where the sheath member covers said tip to prevent needle sticks; and
locking means mounted along said needle shaft which permanently locks the guard member in the second position upon movement of said guard member from the first position to the second position.

12. The device of Claim 11 where the guard member has a collar member and the locking means has a receptacle in which the collar member snaps into upon movement of the guard member into the second position.

13. The device of Claim 13 wherein the locking means includes a ramp section forward of the receptacle over which the collar member rides as it approaches the receptacle, said receptacle having an elevated wall which acts as a stop for the collar member to prevent axial movement of the guard member after the collar member snaps into the receptacle.

14. The device of Claim 11 wherein the receptacle has inwardly tapered walls and the collar has outwardly tapered walls, said receptacle and collar walls abutting each other when the collar member is received in the receptacle.

15. The device of Claim 11 wherein the locking means has a central passageway therethrough which the shaft of the needle passes, with said locking means and needle shaft being bonded to each other.

16. The device of Claim 11 wherein the collar member has an expandable orifice therein and the locking means has a ramp section which fits into and forces expansion of the orifice as the guard member moves into the second position.

17. A medical device used in combination with a medication dispenser, including

connector means having a hub portion with a first end having means for removably attaching the connector means to the dispenser and a second end disposed to the first end, said hub portion having a passageway therein extending between the first and second ends through which medication dispensed by the dispenser may flow;

a metal needle secured to the second end of the barrel portion and in communication with the passageway, said needle having an elongated hollow shaft through which the medication flows and at the end of the shaft an open tip adapted to penetrate the body of a patient and from which the medication exits the needle;

an elongated tubular guard mounted on the shaft of the needle and movable axially along the shaft between a first position where the guard is displaced inwardly from the tip of the needle to enable the needle to penetrate the body of a patient and a second position where the guard covers the needle tip to prevent needle sticks;

said guard having at its rearward end a collar member and at its forward end a restricted opening, with said needle extending through the restricted opening when guard is in the first position to expose said tip and being displaced inwardly from said opening when the guard is in the second position, said opening being sufficiently restricted so that the tip of the little finger of a typical adult user cannot be inserted into the opening and thereby stuck by the tip of the needle;

locking means mounted along the shaft of the needle between the needle tip and the second end of the hub portion which permanently locks the guard in the second position upon movement of the sheath from the first position to the second position, said locking means including a shoulder element which serves to support guard when said guard is in the first position, act as a guide as the guard moves from the first position to the second

position and acts as a stop to prevent further axial movement of the guard when it reaches the second position.

18. The device of Claim 17 including a sheath which fits over the needle to prevent exposure of the needle tip when the guard is in the first position, said cover member having one end closed and opposed open end, said connector means fitting snugly within the open end of the sheath so that the sheath encases the needle and the guard but may be manually removed by pulling it off the connector means.

19. The device of Claim 18 wherein the guard has a collar member and the locking means has a receptacle in which the collar member snaps into upon movement of the guard into the second position and makes an audible sound indicating that the guard is locked safely into position.

20. The device of Claim 19 wherein the locking means has a central passageway through which the shaft of the needle passes, with said locking means and needle shaft being bonded to each other.

FIGURE 1

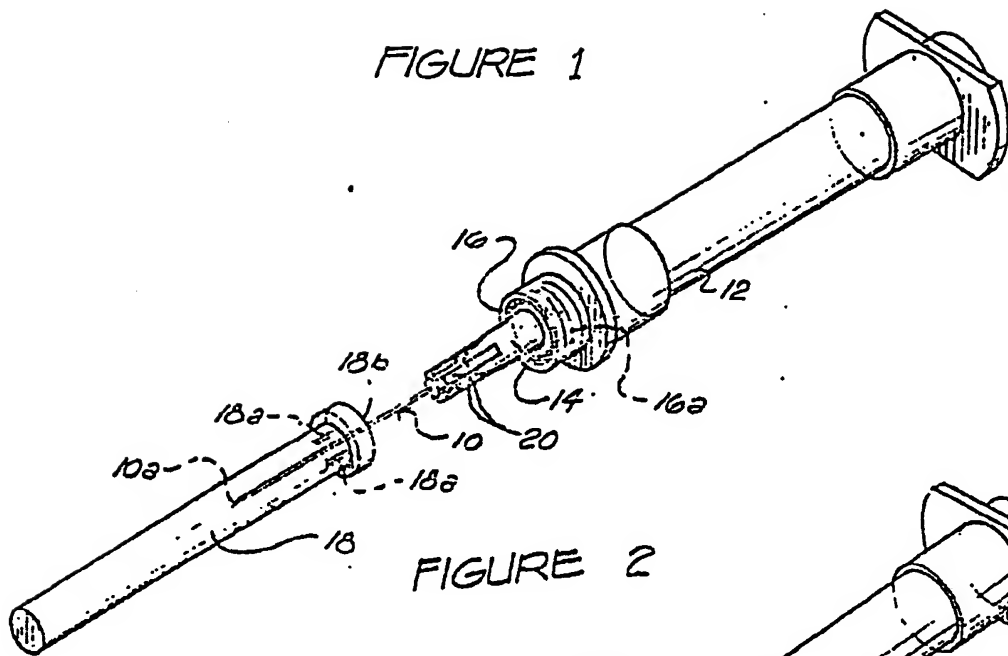


FIGURE 2

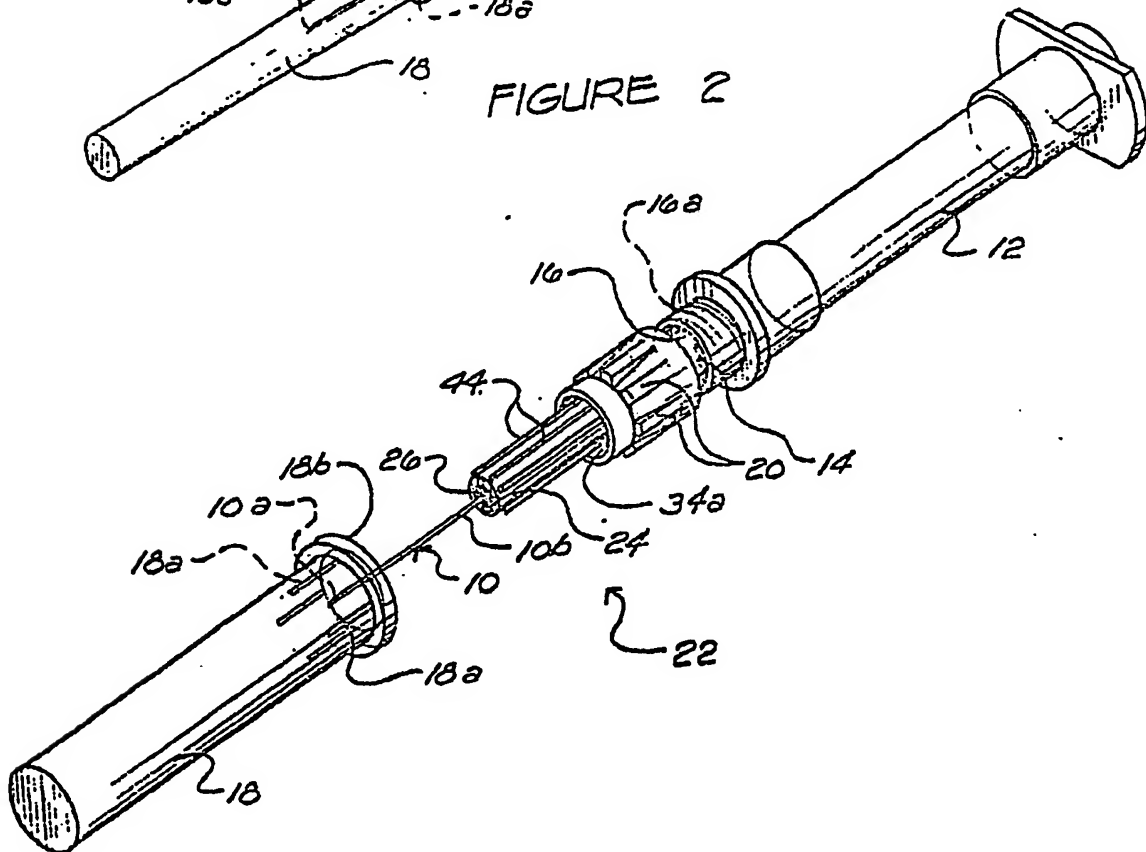


FIGURE 3

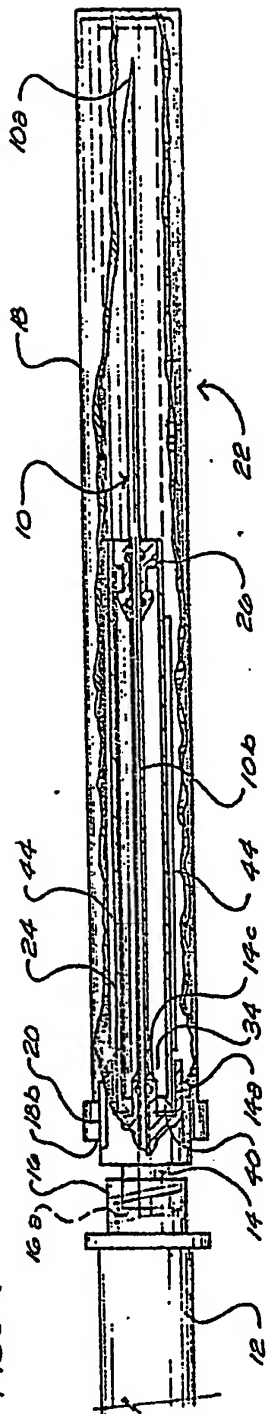


FIGURE 4

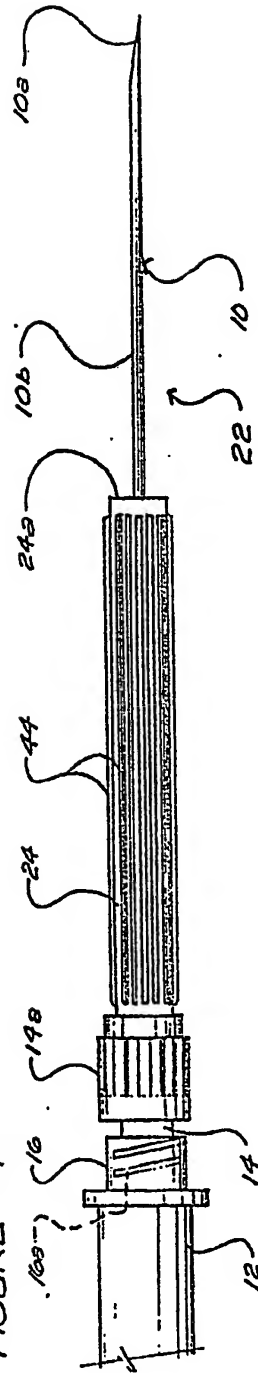
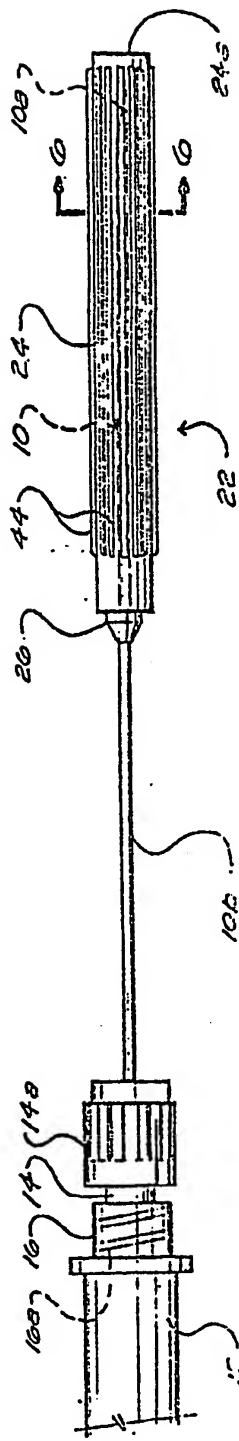


FIGURE 5



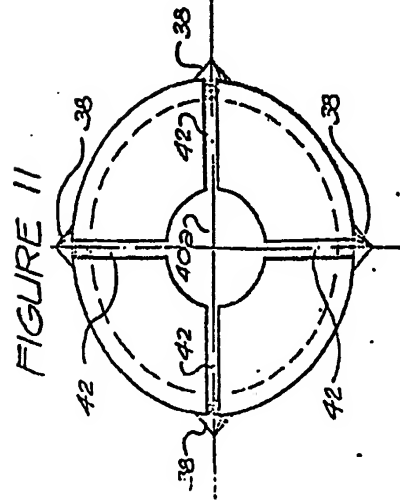
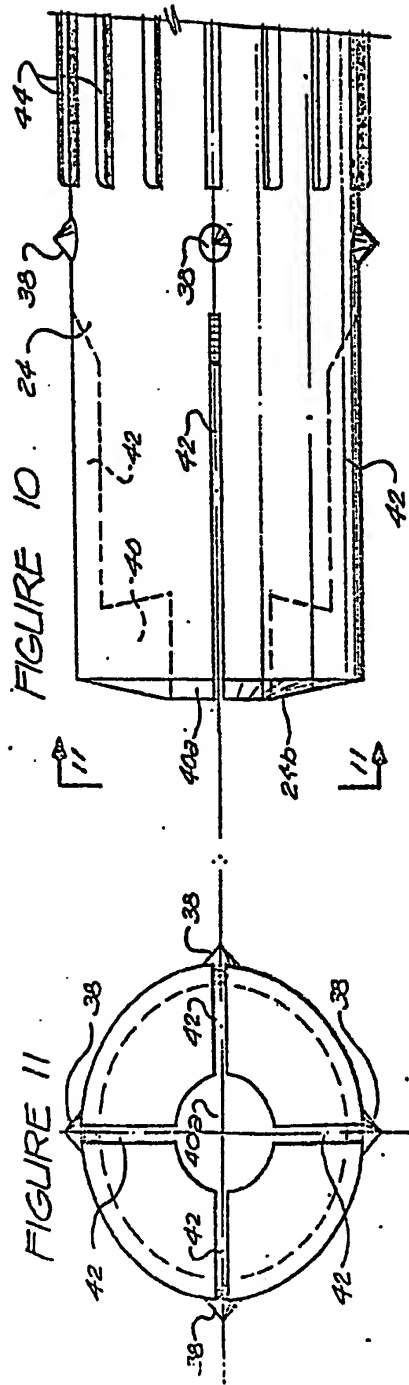
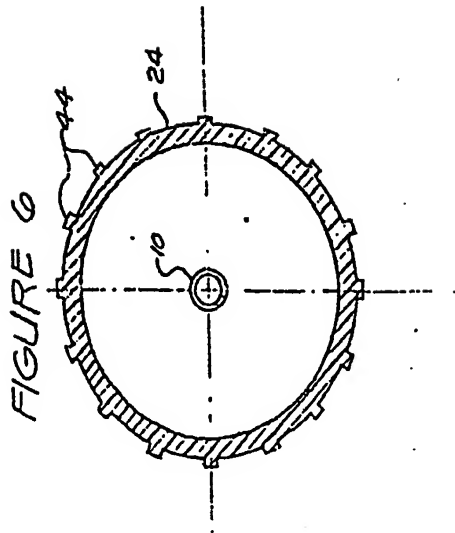


FIGURE 7

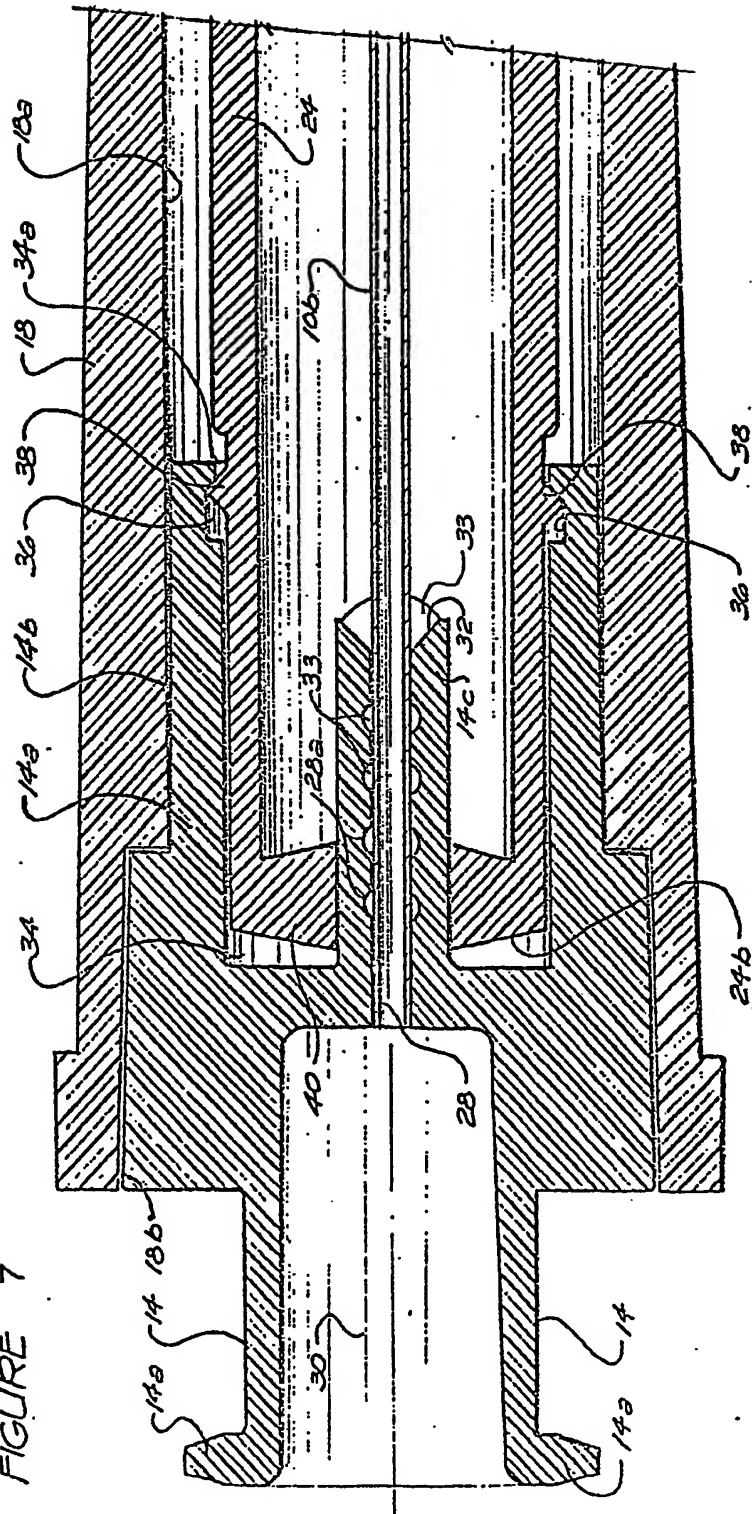
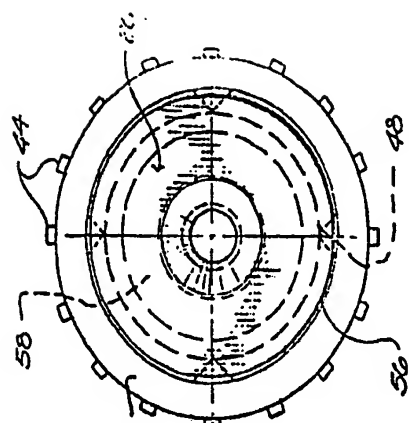
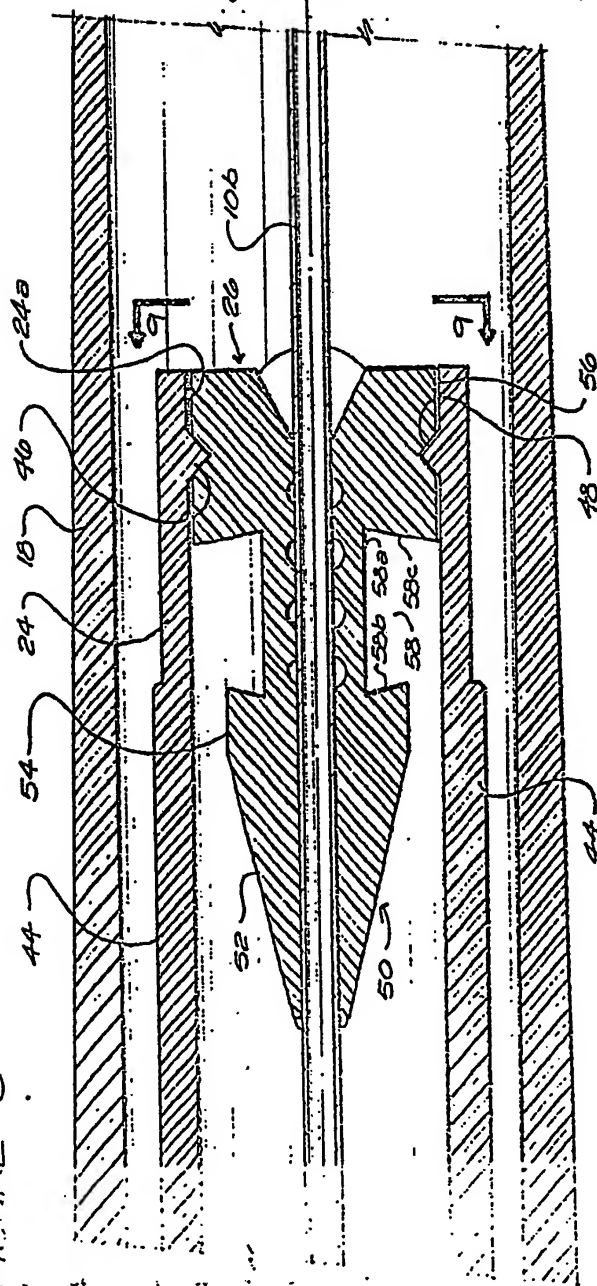


FIGURE 9



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